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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,001	02/20/2003	Andrew Bayliffe	13134-PCT-US	9030

7590

10/17/2005

David A Kalow
Kalow & Springut
19th Floor
488 Madison Avenue
New York, NY 10022

EXAMINER

MYERS, CARLA J

ART UNIT PAPER NUMBER

1634

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,001	BAYLIFFE ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-14, drawn to methods and primers for detecting 5T, 7T and 9T alleles in intron 8 of the CFTR gene.

Group II, claims 15-30, drawn to primers for detecting CRFT alleles DF508, 3849+10kb C>T, N1303K, 1717-1G, W1282X and G542X.

2. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the inventions of group I and II do not share the same linking technical feature because the methods and primers of invention I are directed to the detection of the 5T, 7T and 9T alleles of the CFTR gene, whereas the primers of invention II are directed to the detection of the CRFT alleles DF508, 3849+10kb C>T, N1303K, 1717-1G>A, W1282X

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and G542X. The primers of inventions I and II consist of distinct nucleotide sequence, hybridize to different target sequences, have different melting temperatures and different functions in that they detect different mutations. Further, the primers of invention II were known in the art at the time the invention was made. For instance, EP 0928832 (page 3) teaches the primers for W1282X, G542X, N1303K, 1717-1G>A, DF508 and 3849+10kb C>T. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

Additionally, it is noted that under 37 CFR 1.475(d) Applicant is entitled to an examination of the first product, method of making said product and method of using said product. In the instant Application, the products of group II constitute additional and distinct products. Accordingly, restriction of groups I and II is proper.

Sequence Election Requirement Applicable to All Groups

3. In addition, each invention detailed above reads on patentably distinct inventions drawn to multiple SEQ ID Numbers. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. Although the chemical compounds share a common structure in that they are nucleic acids, the compounds are not regarded as being of a similar nature because all of the alternatives do not share a common property or activity. Each of the nucleic acids consists of a unique nucleotide sequence, has a distinct melting temperature and a distinct specificity of hybridization. A search for polynucleotides comprising the primers for detecting the DF508 mutation would not be co-extensive with a search for polynucleotides comprising

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the primers for detecting the 3849+10kb C>T mutation. Further, a reference rendering the primers for detecting the DF508 mutation as anticipated or obvious over the prior art would not necessarily also render the primers for detecting the 3849+10kb C>T mutation as anticipated or obvious over the prior art. Similarly, a finding that the primers for detecting the DF508 mutation was novel and unobvious over the prior art would not necessarily extend to a finding that the primers for detecting the 3849+10kb C>T mutation was also novel and unobvious over the prior art.

In response to the restriction requirement, Applicant must further elect:

i) with respect to group I, a single primer or set of primers selected from the group of primers recited in claims 2-5 and 8;

ii) with respect to group II, a single primer or set of primers selected from the group of primers recited in claims 15-30.

It is noted that this is a restriction requirement and should **not** be construed as an election of species.

Applicants response should include a statement of the specific claims which read on the elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Further, in response to this Office action, Applicants are required to amend the claims and specification to recite the appropriate sequence identifier adjacent to each of the recited sequences, as required under 37 CFR 1.821(d). See, in particular, Tables 1-5 of the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

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Carla Myers
October 3, 2005

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER